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INSIGHT: With Spotlight on Women's Health, What Litigation Risks Lurk?

BY ROBERT FRIEDMAN AND LISA DWYER

In recent months, greater attention has focused on myriad challenges women face when accessing health care, from discrimination at the doctor's office to a lack of adequate treatment options to insufficient study and understanding of common health problems.

This shift, along with increased activity on these issues at the Food & Drug Administration, has created greater instability and risk in the life sciences industry.

With respect to product liability litigation—particularly mass torts—one way to evaluate this shift is from the perspective of the companies that bring products to market, and the health care providers who incorporate them into their treatment of patients.

Biases in Drug and Medical Device Research & Development Drug development in the U.S. is multi-phase process regulated by FDA. The development process for medical devices is more varied, in part because devices can have vastly different applications. Testing a heart valve might require a very different testing protocol than testing an MRI machine, for example. Yet for both drugs and devices, vestiges of historical gender bias negatively impact women's health.

When it comes to clinical testing, unless the products are intended to treat a condition specific to women, products historically have not been studied in women to the same degree as they have been studied in men.

This is due to a few different factors, including:

1. women of childbearing age often being excluded from clinical trials;

2. women being, or being perceived as, harder to recruit and enroll in clinical trials;

3. a historical and sexist viewpoint that men's health is more important, since men played more ''valuable'' roles in society;

4. concern that women's reproductive cycle and hormones would skew data or make interpretation more complicated; and

5. the false premise that women and men are the same.

While FDA has recently promulgated new guidance regarding the inclusion of women in clinical trials, many decisions about whether and how female subgroup analyses will be performed, and whether those analyses will be meaningful, are left up to drug or medical device researchers.

As a result, the data generated during the product development process may not always be as applicable to women as to men. Drugs may appear safe when studied in men but nevertheless pose increased risks to women. Or, it's possible that even if women were included in studies, the sample size wasn't large enough to detect the risks posed to them.

It is easy to see how these questions can create powerful arguments in lawsuits where it is alleged that the product manufacturer failed to adequately warn of the risks of a product. If a drug or device is alleged to cause an increased risk of a particular adverse event in women (but not men), even if the risk is not specific to women (e.g., arrhythmia), the sponsor's clinical research will be scrutinized: Did they include women? Enough women? Did they do the right subgroup analyses? Could the risk have been identified?

What can product manufacturers do to prepare?

First, be familiar with the clinical information that was collected. Consider whether it can/should be reanalyzed, if possible, to identify any latent risk.

Second, if the data is found to be severely lacking, consider additional post-marketing studies to shore up the data. Pharmacovigilance practices should also be

analyzed to make sure they are appropriately sensitized to sex and gender differences.

Health Care Providers and the Knowledge and Trust Gaps Health care professionals play an important role in controlling patient access to drugs and medical devices, and in litigation that arises when things don't go as hoped. The health care profession has its own history of gender bias in favor of men, which has resulted in a frequent misunderstanding of women's health.

In her insightful book, ''Doing Harm,'' author Maya Dusenbery calls this the ''Knowledge Gap.'' The majority of clinicians, medical educators, journal editors, and nearly every stakeholder group in medicine has historically been men, and they have a natural bias towards men's health issues, Dusenbery explains.

Another significant challenge women face when accessing health care stems from longstanding issues of misogyny: women simply are not afforded the credibility that men are. Dusenbery calls this the ''Trust Gap.'' When women go to the doctor, their complaints are less likely to be taken seriously, their illnesses are diagnosed less quickly, and they are likely to be treated less aggressively than men.

The Trust Gap and Knowledge Gap are exacerbated by the fact that many women are less vocal advocates for their health than men. Women are much less likely to challenge a male doctor's advice than men, less likely to disagree with a doctor's conclusion, and even less likely to meaningfully participate in the discussion. As these issues receive more attention, creative lawyers will see their various utility in litigation.

What Companies Can Do? Combating these arguments—most of which a manufacturer has little control over—can be challenging.

One response might be to demonstrate the efforts a drug or medical device maker has made to address women's health issues; for example, a company could affirmatively introduce post-marketing efforts to ensure female safety.

Companies can embrace the message that women face real challenges in getting their health care needs met, but that the companies are in fact part of the solution, not the problem.

On a more acute level, lawyers confronting doctors both in deposition and at trial need to be experts on the sponsor's clinical research so that they can be prepared to rebut these arguments if they are made.

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